



Certificato UE del Sistema di Gestione della Qualità EU Quality Management System Certificate

Certificato N. /
Certificate No. **0425-MDR-006772-00**

Secondo l'Allegato IX Capo I del Regolamento UE 2017/745
According to Annex IX Chapter I of EU Regulation 2017/745

ORGANISMO NOTIFICATO / NOTIFIED BODY

ICIM S.p.A. - Identification number: 0425
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY

VISTO L'ESITO DELLE VERIFICHE CONDOTTE IN CONFORMITÀ ALL'ALLEGATO IX CAPO I
DEL REGOLAMENTO UE 2017/745 DICHIARA CHE IL SISTEMA DI GESTIONE DELLA QUALITÀ ATTUATO DA:
ON THE BASIS OF THE ASSESSMENT PERFORMED ACCORDING TO ANNEX IX CHAPTER I
OF EU REGULATION 2017/745 DECLARES THAT THE QUALITY MANAGEMENT SYSTEM ENFORCED BY:

Alvimedica Tıbbi Ürünler San. ve Dış Tic. A.Ş.

SEDE LEGALE E UNITÀ OPERATIVA / HEAD OFFICE AND OPERATIVE UNIT
İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540 Çatalca-İstanbul
TÜRKİYE

Numero di Registrazione / Single Registration Number: **TR-MF-000029915**

PER I PRODOTTI, PROCESSI, SERVIZI RIPORTATI NELL'ALLEGATO
FOR THE PRODUCTS, PROCESSES, SERVICES LISTED IN THE ATTACHED ANNEX

INVADER™ PTCA BALLOON DILATATION CATHETER

È CONFORME AI REQUISITI / IS IN COMPLIANCE WITH REQUIREMENTS

Allegato IX Capo I del Regolamento UE 2017/745
Annex IX Chapter I of EU Regulation 2017/745

Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato / This Certificate is valid only with the relative Annex

Per l'immissione sul mercato dei dispositivi di Classe III e di Classe IIb impiantabili coperti dal presente certificato
è necessario un certificato di valutazione UE della documentazione tecnica (Allegato IX Capo II)
For the placing on the market of Class III and Class IIb implantable devices an EU Technical Documentation Assessment certificate is required (Annex IX Chapter II)

Storicità del Certificato / Certificate History

Certificato precedente / Previous certificate	//
Data di rilascio / Issue date	04/07/2023
Modifiche apportate / Changes	Revisione denominazione prodotti / Products name revision.
Test effettuati, riferimenti normativi e rapporti Tests, standards references and reports	//
Informazioni sulla sorveglianza da parte dell'organismo notificato (se applicabile) Information about the surveillance by the notified body (if applicable)	//
Condizioni o limitazioni di validità del certificato (se applicabile) Conditions for or limitations to the validity of the certificate (if applicable)	//

Federico Pasqui

Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE
FIRST ISSUE

04/07/2023

EMISSIONE CORRENTE
CURRENT ISSUE

07/07/2023

DATA DI SCADENZA
EXPIRING DATE

03/07/2028



Certificato UE del Sistema di Gestione della Qualità EU Quality Management System Certificate

ALLEGATO AL / ANNEX TO

Certificato N.
Certificate No.

0425-MDR-006772-00

Secondo l'Allegato IX Capo I del Regolamento UE 2017/745
According to Annex IX Chapter I of EU Regulation 2017/745

IDENTIFICAZIONE TIPOLOGIE E MODELLI IDENTIFICATION OF THE MODEL/TYPE

Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X6 - 512110021610	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X10 - 512110021611	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X12 - 512110021612	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X15 - 512110021613	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X20 - 512110021614	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X6 - 512110021615	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X10 - 512110021616	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X12 - 512110021501	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X15 - 512110021617	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X20 - 512110021502	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X6 - 512110021618	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X10 - 512110021619	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X12 - 512110021503	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X15 - 512110021504	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X20 - 512110021506	Class III	Balloon Dilatation Catheter

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso ¹ Intended purpose ¹
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X25 - 512110021508	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X6 - 512110021620	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X10 - 512110021621	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X12 - 512110021622	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X15 - 512110021623	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X20 - 512110021624	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X25 - 512110021625	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X6 - 512110021626	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X10 - 512110021627	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X12 - 512110021509	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X15 - 512110021510	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X20 - 512110021512	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X25 - 512110021514	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X30 - 512110021516	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X34 - 512110021517	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X6 - 512110021628	Class III	Balloon Dilatation Catheter

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso ¹ Intended purpose ¹
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X10 - 512110021629	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X12 - 512110021551	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X15 - 512110021552	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X20 - 512110021554	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X25 - 512110021556	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X30 - 512110021558	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X34 - 512110021559	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X6 - 512110021630	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X10 - 512110021631	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X12 - 512110021518	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X15 - 512110021519	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X20 - 512110021521	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X25 - 512110021523	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X30 - 512110021525	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00x34 - 512110021526	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X10 - 512110021632	Class III	Balloon Dilatation Catheter

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X12 - 512110021633	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X15 - 512110021634	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X20 - 512110021635	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X25 - 512110021636	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X30 - 512110021637	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X34 - 512110021638	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X10 - 512110021639	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X12 - 512110021527	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X15 - 512110021528	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X20 - 512110021530	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X25 - 512110021532	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X30 - 512110021534	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X34 - 512110021535	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X10 - 512110021640	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X12 - 512110021641	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X15 - 512110021642	Class III	Balloon Dilatation Catheter

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Rappresentante Direzione / Management Representative

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X20 - 512110021643	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X25 - 512110021644	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X30 - 512110021645	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X34 - 512110021646	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X10 - 512110021647	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X12 - 512110021536	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X15 - 512110021537	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X20 - 512110021539	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X25 - 512110021541	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X30 - 512110021543	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X34 - 512110021544	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X10 - 512110021648	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X12 - 512110021546	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X15 - 512110021547	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X20 - 512110021549	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X25 - 512110021649	Class III	Balloon Dilatation Catheter

Federico Pasqui

Rappresentante Direzione / Management Representative

ICIM S.p.A.

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Certificato UE del Sistema di Gestione della Qualità EU Quality Management System Certificate

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Secondo l'Allegato IX Capo I del Regolamento UE 2017/745
According to Annex IX Chapter I of EU Regulation 2017/745

Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X30 - 512110021650	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X34 - 512110021651	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X10 - 512110021652	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X12 - 512110021653	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X15 - 512110021654	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X20 - 512110021655	Class III	Balloon Dilatation Catheter

¹Per dispositivi di Classe IIb e di Classe III / For Class IIb and Class III devices

Federico Pasqui
Rappresentante Direzione / Management Representative

ICIM S.p.A.

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CURRENT ISSUE

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DATA DI SCADENZA
EXPIRING DATE

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**Certificato di valutazione UE della
Documentazione Tecnica
EU Technical Documentation Assessment
Certificate**

Certificato N.
Certificate No. **0425-MDR-006773-00**

Secondo l'Allegato IX Capo II del Regolamento UE 2017/745
According to Annex IX Chapter II of EU Regulation 2017/745

ORGANISMO NOTIFICATO / NOTIFIED BODY

ICIM S.p.A. - Identification number: 0425
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY

ATTESTA AL FABBRICANTE:
CERTIFIES TO THE MANUFACTURER:

Alvimedica Tıbbi Ürünler San. ve Dış Tic. A.Ş.

SEDE LEGALE E UNITÀ OPERATIVA / HEAD OFFICE AND OPERATIVE UNIT
İstanbul Trakya Serbest Bölgesi, Ferhatpaşa SB Mahallesi
Atatürk Bulvarı No:16 34540 Çatalca-İstanbul
TÜRKİYE

Numero di Registrazione / *Single Registration Number:* **TR-MF-000029915**

CHE UN ESAME DELLA DOCUMENTAZIONE TECNICA E' STATO CONDOTTO PER I PRODOTTI, PROCESSI, SERVIZI RIPORTATI
NELL'ALLEGATO E CHE QUESTI SONO CONFORMI AI REQUISITI RIPORTATI IN
*THAT A TECHNICAL DOCUMENTATION EXAMINATION HAS BEEN PERFORMED FOR THE PRODUCTS, PROCESSES, SERVICES
LISTED IN THE ATTACHED ANNEX AND THAT THEY ARE IN COMPLIANCE WITH THE REQUIREMENTS OF*

**Allegato IX Capo II del Regolamento UE 2017/745
Annex IX Chapter II of EU Regulation 2017/745**

Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato / *This Certificate is valid only with the relative Annex*

Per l'immissione sul mercato dei dispositivi di Classe III e Classe IIb impiantabili coperti dal presente certificato è necessario un certificato UE del sistema di gestione della qualità (Allegato IX Capo I) / *For the placing on the market of Class III and Class IIb devices an EU Quality Management System certificate is required (Annex IX Chapter I)*

Storicità del Certificato / *Certificate History*

Certificato precedente / *Previous certificate*

//

Data di rilascio / *Issue date*

04/07/2023

Modifiche apportate / *Changes*

Revisione denominazione prodotti / *Products name revision.*

Test effettuati, riferimenti normativi e rapporti
Tests, standards references and reports

//

Informazioni sulla sorveglianza da parte dell'organismo notificato (se applicabile)
Information about the surveillance by the notified body (if applicable)

//

Condizioni o limitazioni di validità del certificato (se applicabile)
Conditions for or limitations to the validity of the certificate (if applicable)

//

Federico Pasqui

Rappresentante Direzione / *Management Representative*

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Certificato di valutazione UE della Documentazione Tecnica *EU Technical Documentation Assessment Certificate*

ALLEGATO AL / ANNEX TO

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Secondo l'Allegato IX Capo II del Regolamento UE 2017/745
According to Annex IX Chapter II of EU Regulation 2017/745

IDENTIFICAZIONE TIPOLOGIE E MODELLI

IDENTIFICATION OF THE MODEL/TYPE

Dispositivo (nome, modello, tipologia) <i>Device (name, model, type)</i>	Invader™ PTCA Balloon Dilatation Catheter
Classe <i>Class</i>	Class III
Destinazione d'uso <i>Intended purpose</i>	Balloon Dilatation Catheter
UDI-DI di base <i>Basic UDI-DI</i>	086991955InvaderPTCAVA
Documentazione di riferimento <i>Documentation reference</i>	STED-MDR-00002 rev4 on 29 th June 2023

Federico Pasqui
Rappresentante Direzione / Management Representative

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X6 - 512110021610	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X10 - 512110021611	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X12 - 512110021612	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X15 - 512110021613	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.25X20 - 512110021614	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X6 - 512110021615	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X10 - 512110021616	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X12 - 512110021501	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X15 - 512110021617	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 1.50X20 - 512110021502	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X6 - 512110021618	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X10 - 512110021619	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X12 - 512110021503	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X15 - 512110021504	Class III	Balloon Dilatation Catheter

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Certificato di valutazione UE della Documentazione Tecnica EU Technical Documentation Assessment Certificate

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X20 - 512110021506	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.00X25 - 512110021508	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X6 - 512110021620	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X10 - 512110021621	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X12 - 512110021622	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X15 - 512110021623	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X20 - 512110021624	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.25X25 - 512110021625	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X6 - 512110021626	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X10 - 512110021627	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X12 - 512110021509	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X15 - 512110021510	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X20 - 512110021512	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X25 - 512110021514	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X30 - 512110021516	Class III	Balloon Dilatation Catheter

Federico Pasqui
Rappresentante Direzione / Management Representative

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PRIMA EMISSIONE
FIRST ISSUE

04/07/2023

EMISSIONE CORRENTE
CURRENT ISSUE

07/07/2023

DATA DI SCADENZA
EXPIRING DATE

03/07/2028



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Certificato N.
Certificate No.

0425-MDR-006773-00

Secondo l'Allegato IX Capo II del Regolamento UE 2017/745
According to Annex IX Chapter II of EU Regulation 2017/745

Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso ¹ Intended purpose ¹
INVADER™ PTCA BALLOON DILATATION CATHETER 2.50X34 - 512110021517	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X6 - 512110021628	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X10 - 512110021629	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X12 - 512110021551	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X15 - 512110021552	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X20 - 512110021554	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X25 - 512110021556	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X30 - 512110021558	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 2.75X34 - 512110021559	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X6 - 512110021630	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X10 - 512110021631	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X12 - 512110021518	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X15 - 512110021519	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X20 - 512110021521	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X25 - 512110021523	Class III	Balloon Dilatation Catheter

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00X30 - 512110021525	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.00x34 - 512110021526	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X10 - 512110021632	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X12 - 512110021633	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X15 - 512110021634	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X20 - 512110021635	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X25 - 512110021636	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X30 - 512110021637	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.25X34 - 512110021638	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X10 - 512110021639	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X12 - 512110021527	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X15 - 512110021528	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X20 - 512110021530	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X25 - 512110021532	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X30 - 512110021534	Class III	Balloon Dilatation Catheter

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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 3.50X34 - 512110021535	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X10 - 512110021640	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X12 - 512110021641	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X15 - 512110021642	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X20 - 512110021643	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X25 - 512110021644	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X30 - 512110021645	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 3.75X34 - 512110021646	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X10 - 512110021647	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X12 - 512110021536	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X15 - 512110021537	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X20 - 512110021539	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X25 - 512110021541	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X30 - 512110021543	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.00X34 - 512110021544	Class III	Balloon Dilatation Catheter

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PRIMA EMISSIONE
FIRST ISSUE

04/07/2023

EMISSIONE CORRENTE
CURRENT ISSUE

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DATA DI SCADENZA
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Dispositivo – Gruppo di Dispositivi Device – Generic Device Group	Classe / Class	Destinazione d'uso¹ Intended purpose¹
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X10 - 512110021648	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X12 - 512110021546	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X15 - 512110021547	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X20 - 512110021549	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X25 - 512110021649	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X30 - 512110021650	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 4.50X34 - 512110021651	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X10 - 512110021652	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X12 - 512110021653	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X15 - 512110021654	Class III	Balloon Dilatation Catheter
INVADER™ PTCA BALLOON DILATATION CATHETER 5.00X20 - 512110021655	Class III	Balloon Dilatation Catheter

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